

CV22022

Freestone County - District Clerk

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 Teresa Black  
 District Clerk  
 Freestone County, Texas

Katy Conner

NO. CV22022

IVY HIBBARD

VS.

MYLAN PHARMACEUTICALS, INC.,  
 AND MYLAN TECHNOLOGIES, INC.

§ IN THE DISTRICT COURT OF  
 §  
 § FREESTONE COUNTY, T E X A S  
 §  
 § 77TH JUDICIAL DISTRICT

**PLAINTIFF'S ORIGINAL PETITION****TO THE HONORABLE JUDGE OF SAID COURT:**

This case should be governed in accordance with the Discovery Control Plan found in Rule 190.4 of the Texas Rules of Civil Procedure (Level 3).

**PARTIES**

1. The plaintiff, Ivy Hubbard is an individual who resides in Teague, Freestone County, Texas.

2. The defendant, Mylan Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of West Virginia, with its principal place of business in the State of West Virginia, and it have done and continues to do substantial business within the State of Texas within the meaning of TEX. CIV. PRAC. & REM. CODE § 17.041, including certain business transactions from which this action arises. Mylan Pharmaceuticals may be served with process by and through its registered agent, C T Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136.

3. The defendant, Mylan Technologies, Inc., is a corporation organized and existing under the laws of the State of West Virginia, with its principal place of business in the State of West Virginia, and it have done and continues to do substantial business within the State of Texas within the meaning of TEX. CIV. PRAC. & REM. CODE § 17.041, including certain business transactions from which this action arises. Mylan Technologies does not maintain a regular place of business in this state or a designated agent for service of process. Therefore, pursuant to TEX. CIV. PRAC. & REM. CODE §17.044(b), service of citation may be made upon Mylan Technologies by serving the

Exhibit A
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Secretary of State of Texas, Service of Process, James E. Rudder Building, 1019 Brazos, Room 105, Austin, Texas 78701, or P.O. Box 12079, Austin, Texas 78711.

4. The plaintiff seeks damages from Mylan Pharmaceuticals and Mylan Technologies, under three theories of recovery, namely:

- (1) Products liability based upon:
  - (a) Manufacturing defect;
  - (b) Design defect; and
  - (c) Marketing defect.
- (2) Violations of the Deceptive Trade Practice-Consumer Protection Act of the State of Texas (DTPA herein), based upon:
  - (a) Violations of the “laundry list,” §§ 17.46(b)(5), (7), and (23);
  - (b) Breach of the implied warranty of merchantability as established in § 2.314 of the Business and Commerce Act of the State of Texas.
- (3) Negligence in the marketing and the manufacturing of the generic drug, Xulane (norelgestromin and ethinyl estradiol transdermal system), that is the subject of this lawsuit; additionally, invoking the negligence doctrine of *res ipsa loquitur*.

Such damages include actual damages, prejudgment interest, punitive or exemplary damages under the common law; automatic trebling of damages and “additional damages” under the DTPA; and reasonable attorney’s fees through the trial court and through all levels of appeal, if necessary.

5. When it is alleged that Mylan Pharmaceuticals and/or Mylan Technologies committed an act or practice, or by omission failed to act, it is meant that Mylan Pharmaceuticals and/or Mylan Technologies acted or failed to act by and through its agents, servants and employees whose acts or omissions were within the scope of their authority or employment.

6. The cause of action giving rise to this lawsuit, that is, the claims for damages for the injuries sustained by the plaintiff as a result of Mylan Pharmaceuticals' and/or Mylan Technologies' wrongdoing, arose in Freestone County, Texas.

7. Mylan Pharmaceuticals and/or Mylan Technologies were at the time of this occurrence and are now major designers, manufacturers and marketers of Xulane, a birth control drug designed to apply to the skin of a female patient, for sale to and for use by members of the female general public and particularly, by the plaintiff Ivy Hibbard. Additionally, at all times pertinent hereto, Mylan Pharmaceuticals and/or Mylan Technologies were and are merchants with respect to Xulane within the meaning of TEX. BUS. & COM. CODE § 2.314. Mylan Pharmaceuticals and/or Mylan Technologies were, at all times pertinent hereto, marketers and sellers of Xulane.

8. Xulane works by inhibiting an enzyme called *5-alpha reductase*, which converts the male sex hormone *testosterone* into DHT. When a female, such as the plaintiff Ivy Hibbard, is taking Xulane, the female is receiving two female hormones, an estrogen called ethinyl estradiol and a progestin called norelgestromin. Hormones for Xulane get into the female's blood stream and are processed by the body differently than hormones for birth control pills. A female taking Xulane will be exposed to about sixty percent (60%) more estrogen if she uses Xulane than if she were to use a typical birth control pill containing 35 micrograms of estrogen. The increased estrogen intake can increase the risk of side effects to the female patient, including cancers involving the cervix, vagina, and Fallopian tubes.

9. The plaintiff Ivy Hibbard sustained her own injuries after being prescribed and having taken Xulane. The plaintiff was prescribed Xulane as a birth control method on September 20, 2018. She used Xulane for a seven-month period. In 2019 the plaintiff started to experience

pain in her pelvic region. This pain was so severe she had to be treated at an emergency clinic numerous times. On January 31, 2020, Ivy Hibbard's pain still existed but had become so severe she could not walk, stand or move. She again was taken to an emergency room for treatment, where it was thought she had an urinary tract infection. On February 2, 2020, Ivy Hibbard underwent a CT scan at Providence Hospital, Waco, Texas, the results of which revealed she had a large mass on her right ovary. The plaintiff underwent surgery on February 4, 2020, at Providence Hospital for the removal of her right Fallopian tube, where the large mass was actually situated.

10. At all times during the incident made the basis of this lawsuit, Ivy Hibbard was taking Xulane within the intended and anticipated manner prescribed to and contemplated by Mylan Pharmaceuticals and Mylan Technologies.

**COUNT ONE: PRODUCT LIABILITY  
MANUFACTURING DEFECT, DESIGN DEFECT AND  
MARKETING DEFECT**

11. All allegations of fact set forth herein above are adopted into this Count One by reference as though restated herein word for word.

12. The birth control patch Xulane, as manufactured, designed and marketed by Mylan Pharmaceuticals and Mylan Technologies, is defective and unsafe.

13. The defect in the manner in which the birth control patch Xulane was designed or manufactured at the time it left the possession of Mylan Pharmaceuticals and Mylan Technologies rendered Xulane unreasonably dangerous and made it dangerous to an extent beyond which would be contemplated by the ordinary user of the product, including this plaintiff, with the ordinary knowledge common to the community as to the product's characteristics.

14. There was a design defect caused by Mylan Pharmaceuticals and Mylan Technologies at the time Xulane left the possession of Mylan Pharmaceuticals and Mylan Technologies that

rendered Xulane unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use.

15. The design and manufacturing defects in drug Xulane that are involved in this lawsuit existed in the drug Xulane while it was in the hands of Mylan Pharmaceuticals and Mylan Technologies, and such defect rendered the drug Xulane unfit for the ordinary purposes for which it was to have been used by the ultimate user, including this plaintiff, because of a lack of something necessary for adequacy.

16. There was a defect in the marketing of the drug Xulane caused by Mylan Pharmaceuticals and Mylan Technologies at the time it left the possession of Mylan Pharmaceuticals and Mylan Technologies in that there was a failure by Mylan Pharmaceuticals and Mylan Technologies to give adequate warnings of the birth control patch Xulane's dangers that were known by Mylan Pharmaceuticals and Mylan Technologies or by the application of reasonably developed skill and foresight should have been known by Mylan Pharmaceuticals and Mylan Technologies, or there was a failure by Mylan Pharmaceuticals and Mylan Technologies to give adequate instructions to avoid such dangers, which failures rendered the drug Xulane unreasonably dangerous as marketed.

17. The foregoing defects, taken together, separately or in combination, constituted a producing or proximate cause or causes of the plaintiff's damages.

18. Ivy Hibbard did not and in the exercise of reasonable diligence could not have discovered the defects in design, manufacture and/or marketing of the birth control patch Xulane prior to the date she was prescribed the drug and the resulting injuries she sustained; neither did she discover nor in the exercise of reasonable diligence could she have discovered the negligence of Mylan Pharmaceuticals and Mylan Technologies in the design, manufacturing and/or marketing of

the birth control patch Xulane prior to the date she was prescribed the drug and the resulting injuries she sustained.

#### **DAMAGE CLAIMS**

19. Ivy Hibbard's damages exceed the jurisdictional limits of this Court. The plaintiff has been damaged in the following particulars, viz:

- a. Loss of wages in the past and future;
- b. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and supplies in the past;
- c. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and supplies that in all reasonable probability plaintiff will suffer in the future;
- d. Physical pain suffered by the plaintiff in the past;
- e. Physical pain which the plaintiff will in all reasonable probability suffer in the future;
- f. Mental anguish suffered by the plaintiff in the past;
- g. Mental anguish which the plaintiff will in all reasonable probability suffer in the future;
- h. Past impairment suffered by the plaintiff;
- i. Future impairment that will be suffered by the plaintiff in all reasonably probability;
- j. Past disfigurement suffered by the plaintiff; and
- k. Future disfigurement that will be suffered by the plaintiff.

As a result of such particulars, Ivy Hibbard has been damaged in an amount in excess of the minimum jurisdictional limits of this Court.

20. Ivy Hibbard is entitled to recover her actual damages, prejudgment interest, and exemplary or punitive damages as a result of the above allegations of liability and damages. The assessment of any exemplary and/or punitive damages should include evidence of and consideration of reasonable attorney's fees.

**COUNT TWO: VIOLATIONS OF THE DTPA,  
"LAUNDRY LIST" AND THE BREACH OF  
THE STATUTORY IMPLIED WARRANTY  
OF MERCHANTABILITY**

21. All allegations of fact set forth herein above are adopted into this Count of Liability by reference the same as set forth herein word for word.

22. Ivy Hibbard is a "consumer" as to the defendants within the meaning of the DTPA because she was prescribed and purchased the birth control patch Xulane in the transaction which provides the underpinnings of this suit. Xulane, manufactured, designed and marketed by Mylan Pharmaceuticals and/or Mylan Technologies, is a "good" within the meaning of the DTPA.

23. Ivy Hibbard's claims arise out of the good sought or acquired by purchase.

24. Mylan Pharmaceuticals and/or Mylan Technologies represented to Ivy Hibbard that the birth control patch would pass without objection in the trade under the contract description; was fit for the ordinary purposes for which it was intended to be used; would conform to the promises or affirmations of fact made on the labeling and other marketing; that Xulane was of a certain standard, grade or quality, and additionally that Xulane was safe for its intended purpose; that it had uses, qualities and characteristics which it did not have, and that its use in an ordinary situation would be reasonably safe when it was not.

25. Mylan Pharmaceuticals and/or Mylan Technologies failed to disclose to Ivy Hibbard that the birth control patch Xulane was defective in its manufacture and design and that it was unreasonably dangerous. Such information was known to Mylan Pharmaceuticals and Mylan

Technologies at the time of the transaction made the basis of this suit and was withheld with the intent for the plaintiff to enter into the transaction, knowing that he would not have done so if the information had been disclosed.

26. Mylan Pharmaceuticals and Mylan Technologies has violated the DTPA in the following manners that have been and are producing causes of damages to the plaintiff. Their violations include:

- a. Engaging in false, misleading or deceptive acts or practices in the conduct of its trade or commerce with the plaintiff as follows:
  - (1) Representing that the birth control patch Xulane in question was of a certain standard, grade or quality when it was of another.
  - (2) Representing that the birth control patch Xulane had uses, characteristics, and benefits which it did not have.
  - (3) Failing to disclose the true condition of the birth control patch which was known by Mylan Pharmaceuticals and Mylan Technologies at the time in question, thereby intending to induce the plaintiff into the transaction in question into which the plaintiff would not have entered had the information been disclosed.
- b. Breaching the statutory implied warranty of merchantability as set forth in TEX. BUS. & COM. CODE § 2.314.

27. The foregoing acts and omissions were done knowingly by Mylan Pharmaceuticals and Mylan Technologies.

#### **DAMAGE CLAIMS**

28. Ivy Hibbard has been damaged in the following particulars, viz:

- a. Loss of wages in the past and future;
- b. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and



supplies in the past;

- c. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and supplies that in all reasonable probability plaintiff will suffer in the future;
- d. Physical pain suffered by the plaintiff in the past;
- e. Physical pain which the plaintiff will in all reasonable probability suffer in the future;
- f. Mental anguish suffered by the plaintiff in the past;
- g. Mental anguish which the plaintiff will in all reasonable probability suffer in the future;
- h. Past impairment suffered by the plaintiff;
- i. Future impairment that will be suffered by the plaintiff in all reasonably probability;
- j. Past disfigurement suffered by the plaintiff; and
- k. Future disfigurement that will be suffered by the plaintiff.

As a result of such particulars, Ivy Hibbard has been damaged in an amount in excess of the minimum jurisdictional limits of this Court.

29. Ivy Hibbard has been required to engage the services of the undersigned attorneys and have agreed to pay them reasonable fees and expenses for their services. The plaintiff is entitled to recover same against Mylan Pharmaceuticals and Mylan Technologies through all levels of the court process.

30. The plaintiff is entitled to automatic trebling of all actual damages up to \$1,000.00 in actual damages. Additionally, because the acts and omissions of Mylan Pharmaceuticals and Mylan Technologies constituting violations of the DTPA were done knowingly, the plaintiff is entitled to additional damages not to exceed an amount of money equal to twice the amount of actual damages

found by the trier of fact in excess of \$1,000.00.

31. Ivy Hibbard is entitled to pre-judgment interest as allowed by law.

**COUNT THREE: NEGLIGENCE IN  
DESIGN, MANUFACTURING AND MARKETING,  
ASSERTING *RES IPSA LOQUITUR***

32. All allegations of fact set forth herein above are adopted into this Count of Liability by reference the same as set forth herein word for word.

33. Mylan Pharmaceuticals and Mylan Technologies were negligent in designing, manufacturing and marketing the birth control patch Xulane in question in the following respects:

- (1) Mylan Pharmaceuticals and Mylan Technologies were negligent in failing to properly design or compose the birth control patch Xulane.
- (2) Mylan Pharmaceuticals and Mylan Technologies were negligent in offering the birth control patch Xulane for sale to the general public without warning the end users of the birth control patch Xulane.

34. Ivy Hibbard cannot more specifically allege the acts and/or omissions of negligence in the manufacturing and/or design of the birth control patch Xulane in question for the reasons that the facts in that regard are peculiarly within the knowledge of Mylan Pharmaceuticals and Mylan Technologies. In this connection, Ivy Hibbard would show that the design and manufacturing of the birth control patch Xulane was within the exclusive possession and control of Mylan Pharmaceuticals and Mylan Technologies. Ivy Hibbard had no means of ascertaining the method and manner in which the birth control patch was designed, tested and manufactured. The birth control patch was prescribed to and taken as recommended by plaintiff in the same condition it was in when it left the possession and control of Mylan Pharmaceuticals and Mylan Technologies. The occurrence causing the injury to the plaintiff, as described herein, was one which, in the ordinary course of events, would not have occurred without the negligence on the part of Mylan Pharmaceuticals and/or Mylan Technologies in the design and/or manufacturing of the birth

control patch Xulane. Thus the plaintiff is entitled to invoke the negligence doctrine of *res ipsa loquitur*, thereby making Mylan Pharmaceuticals and Mylan Technologies guilty of negligence in the design, manufacturing and marketing of the birth control patch Xulane without further proof, which negligence was a proximate cause of the injuries and damages sustained by the plaintiff.

#### **DAMAGE CLAIMS**

35. Each of said acts and omission contained in this Count, taken singularly or in combination, were a proximate cause of the plaintiff's damages and injuries.

- a. Loss of wages in the past and future;
- b. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and supplies in the past;
- c. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and supplies that in all reasonable probability plaintiff will suffer in the future;
- d. Physical pain suffered by the plaintiff in the past;
- e. Physical pain which the plaintiff will in all reasonable probability suffer in the future;
- f. Mental anguish suffered by the plaintiff in the past;
- g. Mental anguish which the plaintiff will in all reasonable probability suffer in the future;
- h. Past impairment suffered by the plaintiff;
- i. Future impairment that will be suffered by the plaintiff in all reasonably probability;
- j. Past disfigurement suffered by the plaintiff; and
- l. Future disfigurement that will be suffered by the plaintiff.

As a result of such particulars, Ivy Hibbard has been damaged in an amount in excess of the minimum jurisdictional limits of this Court.

36. The foregoing defects were caused or concealed knowingly and as the result of gross negligence. Therefore, Ivy Hibbard is entitled to recover from Mylan Pharmaceuticals and Mylan Technologies exemplary or punitive damages in addition to her actual damages. The assessment of any exemplary and/or punitive damages should include evidence of and consideration of reasonable attorney's fees.

**WHEREFORE, PREMISES CONSIDERED,** Ivy Hibbard, the plaintiff, requests that Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc., the defendants, be cited to appear and answer herein and that on final hearing hereof, the plaintiff has judgment against Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc., for her actual damages and other relief as follows:

- a. An amount in excess of the minimum jurisdictional limits of the Court as compensation for the plaintiff's actual damages;
- b. Pre-judgment interest as allowed by law;
- c. Interest after judgment as allowed by law;
- d. Attorney's fees at all levels of the litigation process;
- e. Automatic trebling of all DTPA damages exceeding \$1,000.00 actual damages; and "additional damages" as allowed under the DTPA; alternatively for exemplary or punitive damages under the common law claims;
- f. Costs of court; and
- g. Such other and further relief, at law or in equity, to which the plaintiffs are justly entitled.

Respectfully submitted,

**THE TRIMBLE FIRM, P.L.L.C.**

*/s/ Dale L. Trimble*

By \_\_\_\_\_

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**JURY TRIAL DEMANDED**